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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,981	06/24/2003	John D. Roback	050508-1031	2039

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EXAMINER

CROSS, LATOYA I

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 12/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/602,981

Applicant(s)

ROBACK ET AL.

Examiner

LaToya I. Cross

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 June 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3-22-04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a) because they fail to show the washer (140) as described in the specification. In the specification, Applicants describe the washer in terms of its size, shape and function (specification page 10). However, in the drawings it appears that the reference character (140), which is described as the washer, points to the filter vessel system and not to a structural element having the size and shape to allow reagents to be washed from the filter vessel. Clarification is requested.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-5, 8, 10-12, 23-31, 35, and 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,620,898 to Yaremko et al.

Yaremko et al teach an automated blood analysis system. The system comprises a microcolumn (122), incubator (200), centrifuge (500), pipette assembly (400), washer (406, 410) and imaging system (606), as recited in claims 1-5. The incubator holds containers/receptacles while reagents and fluids are being dispensed into the containers and incubates the containers,

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(col. 5, lines 39-42). The containers/receptacles are microcolumns having a filter through which the assay sample travels. The filters provide an irregular "bottom" for the vessel, as recited in claim 1. The centrifuge rotates the containers within it (containing the assay sample) to push the cellular material in the sample through the filter material and thus separate the sample, as recited in claims 3, 8, 11 and 12 (col. 13, line 61 – col. 15, line 3). At col. 14, line 61 to col. 15, line 3, the reference teaches centrifuging at a lower speed to push the cells toward the filter and to increase cell to cell contact to achieve maximum reactivity, as recited in claims 24-26, 35, 36 and 38. The imaging system comprises a camera (644) for capturing an image of the analysis of the sample, as recited in claim 4 (col. 15, line 48 – col. 16, line 21). The pipette assembly comprises a pipette (402) and a robot arm (404), as recited in claim 5 (col. 13, lines 1-12). Yaremko et al teach that the system is used for analyzing blood samples and for identifying antibodies and antigens as recited in claim 10.

With respect to the method of claims 23, 28 and 29, Yaremko et al teach providing a filter vessel; adding a blood sample and reagent to the vessel, centrifuging the vessel and analyzing the centrifuged components. With respect to claim 31, Yaremko et al teach that the filter in the microcolumn may be a porous gel material (col. 6, lines 21-32).

4. Claims 1, 6, 7, 9, 13-16, 18-22, 39-45 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,692,702 to Burshteyn et al.

Burshteyn et al teach an apparatus for biological sample preparation and analysis, specifically blood cell analysis. The apparatus of Burshteyn et al comprises sample filter vessel (24). The filter vessel comprises a microporous hollow fiber membrane having a plurality of pores. The porous filter allows the vessel to have an irregular bottom. The porous membrane

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may be a nylon membrane, having a pore size of 0.1-5 microns, as recited in claims 6 and 7 (col. 7, lines 43-59). At col. 15, lines 55-59, Burshteyn et al teach that a vacuum forces causes components of the blood to pass through the filter while retaining cells of interest, as recited in claim 16. A fluorescently-labeled antibody (reagent) is added to the blood sample to form a test mixtures, as recited in claims 15 and 19-22. The test mixture is analyzed with a flow cytometer to quantitatively measure the amount of antigen-specific antibody associated with each cell in the test sample as recited in claims 9, 13, 14 (col. 16, lines 44-52).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 15, 17-22, 34, 39-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yaremko et al in view of US Patent 5,968,731 to Layne et al.

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The disclosure of Yaremko et al is described above. Yaremko et al fail to teach a flow cytometer as the image acquisition system.

Layne et al is directed to an apparatus for automated testing of biological specimens. Layne et al teach that image acquisition in automated analyses allows detection of target individual cells and allows the collection of data to be observed by the user later. Layne et al teach that flow cytometry is suitable for image acquisition (col. 14, lines 14-19; col. 17, lines 34-39). It would have been obvious to one of ordinary skill in the art to modify the Yaremko et al reference by substituting the camera imaging system for a flow cytometry imaging system, as taught by Layne et al. In testing of blood specimens, such a modification would allow the user to detect and analyze individual blood cells.

8. Claim 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yaremko et al in view of US Patent 6,008,040 to Datar.

The disclosure of Yaremko et al is described above. Yaremko et al fail to teach the particular filter materials recited in claims 32-33.

Datar teaches efficient separation of cells, cellular materials and proteins. Specifically, Datar teaches separation devices such as bead columns. Further, Datar teaches that cellulose acetate beads, polyesters, and nylons are suitable for use in separation columns due to their specific chemistries on their contacting surfaces (col. 4, lines 24-41). It would have been obvious to one of ordinary skill in the art to use filter materials, such as cellulose acetates, polyesters, and nylons as the filter material in the microcolumn of Yaremko et al. These materials are known to be suitable in the separation of cellular material. The ordinarily-skilled

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artisan would have expected that these filter materials would perform sufficiently in separating blood cells.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-9 and 14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9, 25-28 of copending Application No. 09/773,826. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of instant application recite a system comprising a filter vessel, wherein an incubator, sample separation system, image acquisition system, and robotic pipettor are separately recited in dependent claims. The independent claim of the '826 application recites all of the separate components together. The instant application is broader in all respects than the claims of the '826 application and thus, the instant application anticipates the claims of the '826 application. See *In Re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993).

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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